

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS,	§	
INC. PINNACLE HIP IMPLANT	§	MDL Docket No.
PRODUCTS LIABILITY	§	
LITIGATION	§	3:11-MD-2244-K
-----	§	
This Order Relates To:	§	
	§	
<i>Lay v. DePuy Orthopaedics, Inc., et al.</i>	§	
No. 3:11-cv-03590-K	§	
	§	
<i>Herlihy-Paoli v. DePuy</i>	§	
<i>Orthopaedics, Inc., et al.</i>	§	
No 3:12-cv-04975-K	§	
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**MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS’
MOTIONS TO DISMISS AND FOR SUMMARY JUDGMENT**

Before the Court are five motions of Defendants to dismiss and for summary judgment in *Lay v. DePuy Orthopaedics, Inc., et al.*; No. 3:11-cv-03590-K (“Lay”) and *Herlihy-Paoli v. DePuy Orthopaedics, Inc., et al.*; No. 3:12-cv-04975-K (“Paoli”). For the reasons set forth herein, the motions are **DENIED**.

Defendants filed the following dispositive motions which are the subject of this Order:

1. Motion to dismiss Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, and DePuy Synthes, Inc. because this Court lacks personal jurisdiction over them or, in the alternative, motion for summary judgment because they did not manufacture, sell, or otherwise market the Pinnacle Device [Lay Dkt. No. 66; Paoli Dkt No. 59];

2. DePuy’s motion for partial summary judgment on Plaintiffs’ claims for

medical monitoring and future medical damages [Lay Dkt. No. 61; Paoli Dkt No. 54];

3. DePuy's motion for summary judgment on claims sounding in failure to warn, misrepresentation, or omission [Lay Dkt. No. 59; Paoli Dkt No. 52];

4. DePuy's motion for summary judgment on Plaintiffs' claims for intentional infliction of emotional distress, breach of the implied warranty of fitness, and *res ipsa loquitur* [Lay Dkt. No. 64; Paoli Dkt No. 57]; and

5. DePuy's motion for partial summary judgment on Plaintiffs' design-defect claims [Lay Dkt. No. 68; Paoli Dkt No. 61].

I. PROCEDURAL AND FACTUAL BACKGROUND

The relevant procedural and factual background is provided in the Court's Memorandum Opinion and Order Denying Defendant DePuy Orthopaedics, Inc.'s Motions to Exclude Expert Testimony [Dkt. No. Lay Dkt. No. 98; Paoli Dkt No. 91] and is incorporated by reference.

II. BURDEN OF PROOF

A. Motion to Dismiss

When a non-resident challenges personal jurisdiction under rule 12(b)(2) of the Federal Rules of Civil Procedure, this Court makes a two-step inquiry in determining whether there is personal jurisdiction. *Gartin v. Par Pharm. Cos., Inc.*, 561 F. Supp. 2d 670, 674 (E.D. Tex. 2007), *aff'd*, 289 Fed. Appx. (5th Cir. 2008). First, this Court determines whether the long-arm statute of the forum state permits the exercise of jurisdiction. *Id.* Second, this Court determines whether the exercise of jurisdiction comports with due process. *Id.* MDL courts apply the long-arm statute of the transferor

forum. *Holizna v. Boston Scientific Corp.*, 2013 WL 1411656 at *3 (S.D. W. Va. April 8, 2013). Plaintiffs' cases were transferred from Montana, so Montana's long-arm statute applies; however, Fifth Circuit law applies for the due process analysis. *Id.* In this case, these two steps merge into a single analysis because Montana's long-arm statute has been construed to allow the "exercise of personal jurisdiction over nonresident defendants to the maximum extent permitted by federal due process." *King v. American Family Mut. Ins. Co.*, 632 F.3d 570, 578-79 (9th Cir. 2011). Accordingly, the personal jurisdiction inquiry in this case is governed by federal due process limits as construed by the Fifth Circuit. *Holzina*, 2013 WL 1411656 at *3.

The Due Process Clause permits the exercise of personal jurisdiction over a non-resident when (1) the defendant has established minimum contacts with the forum state and (2) the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice. *Kelly v. Syria Shell Petroleum Dev't, B.V.*, 213 F.3d 841, 854 (5th Cir. 2000). The minimum contacts requirement can be established through specific or general jurisdiction. *Id.* Specific jurisdiction is appropriate when a non-resident corporation has purposefully directed its activities at the forum state and the litigation results from alleged injuries that arise out of or relate to those activities. *Id.* General jurisdiction exists when the non-resident defendant's contacts with the forum state are continuous and systematic although not necessarily related to the litigation. *Id.*

B. Motions for Summary Judgment

This Court shall grant summary judgment if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). An issue as to a material fact is genuine if a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). This Court considers all evidence in the light most favorable to the party resisting the motion. *Trevino v. Celanese Corp.*, 701 F.2d 397, 407 (5th Cir. 1983).

III. ANALYSIS

A. Defendants' Motion to Dismiss or, Alternatively, for Summary Judgment

Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, and DePuy Synthes, Inc. ("Johnson & Johnson Companies") contend this case should be dismissed against them under rule 12(b)(2) of the Federal Rules of Civil Procedure because this Court lacks personal jurisdiction over them. The Johnson & Johnson Companies contend that they have no contacts with Montana, the forum state, or with Texas, where the cases will be tried. None of the Johnson & Johnson Companies is incorporated or has its principal place of business in Texas or Montana. The Johnson & Johnson Companies contend they are all holding/parent companies or service providers that do not manufacture, distribute, or sell products like the Pinnacle Device. Johnson & Johnson International is a subsidiary of Johnson & Johnson; DePuy Synthes, Inc. is a subsidiary of Johnson & Johnson International; and DePuy, the

manufacturer and seller of the Pinnacle Device, is a subsidiary of DePuy Synthes, Inc. Johnson & Johnson Services, Inc. provides services to various Johnson & Johnson subsidiaries, and those services are paid for by the subsidiaries. As such, they contend that they lack contacts with either forum and this Court should dismiss the claims against them for want of personal jurisdiction.

The evidence shows that the Johnson & Johnson Companies (1) hosted a nationwide satellite telecast to physicians all over the country, including Montana, to tout the advantages of the Pinnacle Device, including representations of the benefits of metal-on-metal hip replacements and fluid film lubrication that are in issue in this case; (2) gave direction regarding advertising content and appearance for the Pinnacle Device; (3) made a website available to DePuy for doctors and patients and anyone else seeking information to view advertisements about the Pinnacle Device; (4) placed their name on all Pinnacle Device advertising, literature, products, and packaging that contained representations that are in issue in this case and that were distributed across the country, including in Montana, for health care providers and doctors like Dr. Allmacher to see. Plaintiffs' claims against the Johnson & Johnson Companies include fraud-based claims arising from their involvement in the alleged formulation and dissemination of a campaign of misinformation regarding the safety of the Pinnacle Device. The Fifth Circuit has held that the distribution of false information to consumers within a state will subject a defendant to the jurisdiction of the courts of that state. *Guidry v. United*

States Tobacco Co., Inc., 188 F.3d 619, 628 (5th Cir. 1999). The evidence in this case is sufficient to establish minimum contacts through specific jurisdiction by the Johnson & Johnson Companies' marketing activities with respect to the Pinnacle Device.

The Johnson & Johnson Companies do not assert in their motion to dismiss that the exercise of jurisdiction over them in this case offends traditional notions of fair play and substantial justice. Accordingly, this Court need not address that issue. The Johnson & Johnson Companies' motion to dismiss for lack of personal jurisdiction is, therefore, **DENIED.**

In the event this Court finds jurisdiction over them, the Johnson & Johnson Companies move for summary judgment on all of Plaintiffs' causes of action against them, which they categorize as either product liability claims or fraud claims. First, they contend that the product liability claims fail because none of the Johnson & Johnson Companies manufactured or sold the Pinnacle Device. Second, they argue that the fraud claims fail because Plaintiffs have not identified any misrepresentation that the Johnson & Johnson Companies made upon which Plaintiffs relied.

The Montana Supreme Court has adopted Restatement (Second) of Torts §876 (1979). *Sloan v. Fauque*, 784 P.2d 895, 896 (Mont. 1989). Section 876(b) provides that a party is subject to liability for harm to a third person resulting from the tortious conduct of another if he knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself. This

section of the Restatement has recently been applied to business organizations by the Montana Supreme Court. *Newmann v. Lichfield*, 272 P.3d 625, 633-34 (Mont. 2012).

Sloan and *Newmann* establish that under Montana law liability exists when the defendant knows the other party is breaching a duty but nevertheless provides assistance to that party. *Sloan*, 784 P.2d at 896; *Newmann*, 272 P.2d at 633. The summary judgment evidence in this case raises fact issues that the Johnson & Johnson Companies knew that DePuy was engaged in the manufacture and marketing of a defective product and that they provided assistance to DePuy in marketing that product:

1. The Johnson & Johnson Companies knew that patients in the United Kingdom were experiencing problems with a prior hip implant, a metal-on-metal hip implant device previously manufactured and sold by Johnson & Johnson (not DePuy), yet they obtained FDA approval of the Pinnacle Device based on its substantial equivalence to the prior hip implant device and failed to disclose the problems.

2. After Johnson & Johnson acquired DePuy in 1998, DePuy took over its hip implant business, but Johnson & Johnson continued to exercise control over advertising and marketing as well as intervening in crisis management resulting from a predecessor hip implant failure and recall.

3. The Johnson & Johnson Companies provided marketing assistance to DePuy by allowing the Johnson & Johnson name to be placed on the packaging for the Pinnacle Device and all advertising materials, encouraging the sales force to steer physicians towards use of the Pinnacle Device, sponsoring a satellite telecast to over 1500 doctors in 86 different locations in North America about the Pinnacle Device, being involved in decisions relating to advertising and marketing of the Pinnacle Device, making the Johnson & Johnson website available to DePuy to view advertisements for the Pinnacle Device, and placing the Johnson & Johnson name on the device itself.

This summary judgment evidence is sufficient to raise a fact issue with regard to the Johnson & Johnson Companies' joint liability on Plaintiffs' product liability claims

against DePuy. The Johnson & Johnson Companies motion for summary judgment on Plaintiffs' product liability claims is, therefore, **DENIED**.

Similarly, the summary judgment evidence raises fact issues with respect to Plaintiffs' fraud based claims against the Johnson & Johnson Companies. The summary judgment record raises issues with respect to the truthfulness of the fluid film lubrication theory that was introduced at the Johnson & Johnson organized and sponsored satellite broadcast to over 1500 physicians in 86 different locations. The summary judgment evidence raises fact issues with respect to the truthfulness of numerous statements in DePuy's advertising materials and literature such as the 99.9% five-year survival rate, over which the Johnson & Johnson Companies had authority or sponsored.

There is also summary judgment evidence raising a fact issue about whether Plaintiffs' physician, Dr. Allmacher, relied on these statements when he chose to use the Pinnacle Device for Plaintiffs. The Johnson & Johnson Companies contend that there was no reliance because Dr. Allmacher testified that he did not review any advertising materials from DePuy in determining to use the Pinnacle Device. Dr. Allmacher did testify, however, that he relied on his DePuy representative, Andy Seaman. Mr. Seaman was present for all the surgeries implanting the Pinnacle Device performed by Dr. Allmacher, visited Dr. Allmacher at his office on a regular basis, and was available to Dr. Allmacher as a source of information and to answer questions about the Pinnacle Device. Dr. Allmacher expected Mr. Seaman to bring him information about the Pinnacle

Device, whether positive or negative. Dr. Allmacher also testified that he did a fellowship with a DePuy paid consultant and attended programs given by other DePuy surgical consultants. The evidence shows that he relied on peer-reviewed journals, studies, and presentations about the Pinnacle Device. The evidence suggests that these activities were often sponsored by DePuy and used as marketing vehicles to convey DePuy marketing messages. The Johnson & Johnson Companies' motion for summary judgment on Plaintiffs' fraud based claims is, therefore, **DENIED**.

B. DePuy's Motion for Partial Summary Judgment on Plaintiffs' Claims for Medical Monitoring and Future Medical Damages

DePuy moves for partial summary judgment on Plaintiffs' claims of medical monitoring and future medical damages because they are based on a speculative theory that exposure to cobalt and chromium while implanted with the Pinnacle Device puts them at risk for a number of systematic illnesses in the future. DePuy contends that neither law nor science supports these damages. DePuy additionally argues that there is no cause of action for medical monitoring under Montana law.

Montana law permits the recovery of future damages. MONT. CODE ANN. §27-1-203; *Frisnegger v. Gibson*, 598 P.2d 574, 582 (Mont. 1979). Future medical damages under Montana law include the reasonable value of necessary expenses to the plaintiff for any medical, surgical, hospital, and other services and care and supplies, which the fact-finder determines to be reasonably certain to be required in the future in the treatment of the plaintiff as a proximate result of the injury in question. *Johnson v.*

United States, 510 F. Supp. 1039, 1045 (D. Mont. 1981), *aff'd in part, rev'd in part on other grounds*, 704 F.2d 1431 (9th Cir. 1983). The Montana Supreme Court has repeatedly held that future damages need only be reasonably certain and not absolutely certain. *Frisnegger*, 598 P.2d at 582. The Montana Supreme Court recognizes that future damages may involve some amount of conjecture or speculation but that this is not a basis to preclude them:

[I]t must be granted that in determining an award for future damages, a jury, or an expert testifying on the subject, must to some degree engage in conjecture or speculation. When the conjecture and speculation is based upon reasonably certain human experience as to future events, the jury or trier of fact is entitled to rely on that degree of reasonable certainty in fixing and awarding future damages. *Id.*

DePuy seems to include in its motion for partial summary judgment only those items of future medical expenses relating to future systematic illnesses. Plaintiffs have represented that the only future medical costs relating to future systematic illnesses that they intend to seek are costs for monitoring their blood for cobalt and chromium levels, not costs of care for a future systematic illness. Plaintiffs do not rely on a separate cause of action for medical monitoring to recover these costs but contend that such costs are recoverable as future medical damages under Montana law. Accordingly, this Court will discuss the motion for partial summary judgment with respect to the costs to monitor the cobalt and chromium levels in Plaintiffs' blood as future medical expenses.

The summary judgment record contains evidence that cobalt and chromium are

toxic at certain doses and that Mrs. Lay and Mrs. Paoli suffered metallosis and high cobalt levels as a result of their Pinnacle Devices. In addition, the life care plans prepared for Plaintiffs by their experts indicate that they will need additional monitoring by their primary care physicians to check their chromium and cobalt levels related to metallosis. These experts believe that there is enough concern about the potential long term effects of cobalt and chromium to include future screening in the life care plans. DePuy argues that there is no need for future testing because Plaintiffs' blood levels for chromium and cobalt are too low and their devices were removed over three years ago. The summary judgment evidence shows that the threshold DePuy advocates is applicable for ingested or inhaled exposures to cobalt but not a localized exposure at the hip area. This Court finds that the summary judgment evidence, viewed in the light most favorable to Plaintiffs, raises fact issues as to whether it is reasonably certain that Plaintiffs can recover costs for blood testing for cobalt and chromium as part of future damages. DePuy's motion for partial summary judgment on this issue is, therefore, **DENIED**.

C. DePuy's Motion for Summary Judgment on Plaintiffs' Claims Sounding in Failure to Warn, Misrepresentation, or Omission

DePuy moves for summary judgment on Plaintiffs' claims sounding in failure to warn, misrepresentation, or omission. Specifically, DePuy contends that it is entitled to summary judgment on Plaintiffs' claims for negligence, strict liability, intentional misrepresentation, constructive fraud, violation of the Montana Consumer Protection Act, deceit, fraudulent concealment, negligent misrepresentation, breach of express

warranty, and actual fraud because Plaintiffs cannot prove that Dr. Allmacher, Plaintiffs' implanting physician, relied on DePuy's warnings and representations regarding the Pinnacle Device or that the warnings and representations caused him to choose the Pinnacle Device. DePuy contends that the evidence shows that Dr. Allmacher did not rely on DePuy's marketing materials and never read the "Instructions for Use" that accompanied the Pinnacle Device but instead relied on his own independent research. DePuy argues, therefore, that Plaintiffs cannot prove causation or reliance in these claims. DePuy additionally argues that Plaintiffs' claims for negligent misrepresentation also fail because Montana law limits these claims to advice in connection with a business transaction.

Causation and Reliance

The summary judgment evidence viewed in the light most favorable to Plaintiffs shows:

1. Dr. Allmacher had a close relationship with his DePuy salesman, Andy Seaman, seeing each other on a regular basis for 11 years. Dr. Allmacher relied on Mr. Seaman for information and trusted him to bring to his attention the information he needed to know about the Pinnacle Device, including complications of soft tissue injuries from metal-on-metal devices, but he never did.

2. DePuy paid doctors to market and present DePuy products through what appeared to be neutral, even peer-reviewed sources such as continuing medical education, lectures, articles, and surgeon dinners, many of which Dr. Allmacher testified he was exposed to and upon which he relied.

3. DePuy placed advertisements and other sales pieces in medical journals, brochures, and other materials in order to market DePuy's messages as scientific reports and publications. Dr. Allmacher testified that he reviewed some of these materials.

4. DePuy made false claims regarding the wear rates, fluid film lubrication, and survivorship of the Pinnacle Device through its satellite presentation, paid consultants, continuing medical education seminars, and published articles that Dr. Allmacher relied upon in using the Pinnacle Device in Plaintiffs.

5. Dr. Allmacher was a student and trainee of Dr. Brian Haas, a DePuy paid consultant.

Considering all this evidence, this Court finds that a reasonable jury could determine that Dr. Allmacher relied upon DePuy's misrepresentations and omissions concerning the Pinnacle Device.

Depuy argues that the single fact that Dr. Allmacher did not read the Instructions for Use ("IFU") that accompanied the Pinnacle Device is dispositive of this issue. DePuy relies on *Oakberg v. Zimmer, Inc.*, 211 Fed. Appx. 578 (9th Cir. 2006) in support of its argument that because Dr. Allmacher failed to read the IFU, there is no causation and no reliance. In *Oakberg*, the trial court granted summary judgment in favor of the defendant on Oakberg's negligence claim alleging failure to warn in a products liability case involving the Zimmer Centralign Precoact femoral stem hip implant. *Id.* at 579. This Court acknowledges that in *Oakberg* it was undisputed that neither the implanting doctor nor the patient read the Centralign package insert and that the court found there could be no reliance with respect to Oakberg's failure to warn claim. *Id.* at 581. The IFU in *Oakberg*, however, contained no warning. *Id.* In addition, *Oakberg* is an unpublished memorandum opinion in which the Ninth Circuit Court states, "This disposition is not appropriate for publication and may not be cited to or by the courts

of this circuit . . .” *Id.* at 579. This Court is not bound by the decision in *Oakberg*. Based on the summary judgment evidence before this Court, DePuy’s motion for summary judgment on Plaintiffs’ claims sounding in failure to warn, misrepresentation, and omission based on causation and reliance are denied.

Negligent Misrepresentation

The Montana Supreme Court has adopted section 552 of the Restatement (Second) of Torts. *State Bank of Townsend v. Maryann’s, Inc.*, 664 P.2d 295, 301 (Mont. 1983). That section provides:

One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise care or competence in obtaining or communicating the information.

Restatement (Second) Torts §552. The Montana Supreme Court subsequently expanded this definition by adopting the following elements of negligent misrepresentation:

1. A representation as to a past or existing material fact;
2. The representation must be false;
3. The representation must have been made without any reasonable ground for being true;
4. The representation must have been made with the intent to induce the plaintiff to rely on it;
5. The plaintiff must have been unaware of the falsity of the representation and justifiably relied on its truth; and,

6. The plaintiff suffered damages as a result of the reliance.

Kitchen Krafters, Inc. v. Eastside Bank of Montana, 789 P.2d 567, 673 (Mont. 1990), overruled in part on other grounds, *Busta v. Columbus Hospital*, 916 P.2d 122, 139 (Mont. 1996). These elements of negligent misrepresentation do not include business transactions.

In *Morrow v. Bank of America*, 324 P.3d 1167 (Mont. 2014), the Montana Supreme Court recently recognized that *Kitchen Krafters* expanded the Restatement definition of negligent misrepresentation and that negligent misrepresentations may occur outside the context of business transactions. *Morrow*, 324 P.3d at 1180; *Jackson v. Dep't of Family Svcs.*, 956 P.2d 35 (Mont. 1998) (applying *Kitchen Krafters* elements of negligent representation to claims by prospective parents about adoption process). At the same time, the court noted that the Restatement definition is still applied in some cases, particularly in the context of professional negligence. *Morrow*, 324 P.3d at 1180. The court held:

We are faced today with defining the appropriate duty of care owed by a bank to its customers, and so we find it necessary to resolve this disparity [between the Restatement definition and *Kitchen Krafters*] with respect to banking transactions. We hold that a claim of negligent misrepresentation against a financial institution is governed by the definition in the Restatement (Second) of Torts . . . *Id.*

Based on the Montana Supreme Court's opinion in *Morrow*, this Court cannot conclude that Montana's negligent misrepresentation claims are limited to business transactions as DePuy argues. Instead, Montana has expanded its negligent misrepresentation cause

of action by evaluating the duty of care owed between the parties and applying the appropriate standard. DePuy's motion for summary judgment on Plaintiffs' negligent misrepresentation claim is, therefore, **DENIED**.

D. DePuy's Motion for Summary Judgment on Plaintiffs' Claims for Intentional Infliction of Emotional Distress, Breach of the Implied Warranty of Fitness, and *Res Ipsa Loquitur*.

DePuy moves for summary judgment on Plaintiffs' claims for intentional infliction of emotional distress, breach of the implied warranty of fitness, and *res ipsa loquitur*. DePuy first argues that it cannot be held liable for intentional infliction of emotional distress because Plaintiffs cannot demonstrate that DePuy engaged in intentional conduct specifically directed at them for the purpose of causing them emotional distress. Second, DePuy contends that Plaintiffs cannot recover for breach of the implied warranty of fitness because they have not identified a particular or special purpose, as distinguished from an ordinary purpose, for which their hip implants were intended to be used. Finally, DePuy argues that *res ipsa loquitur* is not a cause of action under Montana law but, upon the proper showing, is more appropriately an evidentiary instruction to the jury in connection with Plaintiffs' negligence claim.

Intentional Infliction of Emotional Distress

In 1995, the Montana Supreme Court established a cause of action for intentional infliction of emotional distress. *Sacco v. High Country Independent Press*, 896 P.2d 411 (Mont. 1995). Such an action arises when a plaintiff suffers serious and emotional

distress as a reasonably foreseeable consequence of a defendant's intentional act or omission. *Id.* at 428. The Montana Supreme Court consistently relies on Restatement (Second) Torts §46(1) for guidance in emotional distress claims. *Czajkowski v. Meyers*, 172 P.3d 94, 101 (Mont. 2007). That section provides that “[o]ne who by extreme and outrageous conduct intentionally or recklessly causes severe emotional distress to another is subject to liability for such emotional distress, and if bodily harm to the other results from it, for such bodily harm.” Restatement (Second) Torts §46(1) (emphasis added).

Under section 46(1), a defendant can cause severe emotional distress to another by either intentional or reckless conduct. While this Court has been unable to find any Montana law addressing this reckless requirement, at least one other court has held that recklessness does not require the actor to aim the conduct toward a specific person or a specific result because to do so would contradict the inattentive and thoughtless nature of disregard and relegate it to the same scope as intentional conduct. *Doe I ex rel. Doe I v. Roman Catholic Diocese of Nashville*, 154 S.W.3d 22, 36 (Tenn. 2005). The directed-at requirement is incompatible with the concept of recklessness. *Id.* at 37. Because section 46(1) provides two different methods by which a plaintiff may prove an intentional infliction of emotional distress claim, DePuy's motion for summary judgment contending that such claim may only be proven by intentional conduct directed at Plaintiffs is **DENIED.**

Even if Montana law requires only specific conduct directed to Plaintiffs for a cause of action for intentional infliction of emotional distress, DePuy's motion for summary judgment on this claim is still without merit. The summary judgment evidence raises fact issues that while DePuy's conduct may not have been directed specifically at Ms. Lay and Ms. Paoli, it was certainly directed at persons like them who were young, active individuals in need of hip replacement surgery. DePuy's website, hipreplacement.com, targets young, active patients by touting the longer survivorship rate for metal-on-metal devices. Ms. Paoli testified that she recalls seeing information that led her to believe that metal-on-metal hip replacements would last longer. DePuy's motion for summary judgment on Plaintiffs' intentional infliction of emotional distress claim is **DENIED**.

Breach of Implied Warranty of Fitness

Section 30-2-315 of the Montana Code recognizes an implied warranty that goods will be fit for a particular purpose "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods" MONT. CODE ANN. §30-2-315. A "particular purpose" contemplates a specific use by the buyer which is peculiar to the nature of his business, while the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in questions. MONT. CODE ANN.

§30-2-315, cmt. 2. An example in the comment to section 30-2-315 involves shoes that are generally used for walking upon ordinary ground, but a seller may know that a particular pair was selected for use in climbing mountains. *Id.*

Defendants argue that summary judgment is proper on Plaintiffs' claim for breach of the implied warranty for a particular purpose because there is no evidence that Plaintiffs or their doctor made DePuy aware that the Pinnacle Device would be used for anything other than its ordinary purpose—to implant as a hip replacement. In other words, remote manufacturers like DePuy could never be liable for breach of implied warranty for a particular purpose because they never deal directly with plaintiffs. This argument has been rejected by the Montana Supreme Court. *Streich v. Hilton-Davis, Division of Sterling Drug, Inc.*, 692 P.2d 440, 448 (Mont. 1984); *Whitaker v. Farmhand, Inc.*, 567 P.2d 916, 920 (Mont. 1977). The Montana Supreme Court in *Whitaker* relied on the New Jersey Supreme Court decision in *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960). *Whitaker*, 567 P.2d at 920. In *Henningsen*, the court held that “when a manufacturer puts a new automobile in the stream of trade and promotes its purchase by the public, an implied warranty that it is reasonably suitable for use as such accompanies it into the hands of the ultimate purchaser.” *Henningsen*, 161 A.2d at 84. In other words, *Henningsen* establishes that liability for breach of the implied warranty for a particular purpose runs against a manufacturer who may never have met the plaintiff and has no direct knowledge of the particular purpose for which the plaintiff

intends to use the product. Such a manufacturer, however, warrants that the product was fit for a particular purpose, at least where the product was used in a manner foreseen by the manufacturer. *Id.* at 83.

The summary judgment evidence raises fact issues that Plaintiffs used the Pinnacle Device for a “particular purpose” instead of just its “ordinary purpose” and that DePuy knew about it. DePuy marketed the Pinnacle Device specifically to young, active patients because of its longer survivorship rate—patients like Ms. Lay and Ms. Paoli. Viewing the evidence in the light most favorable to Plaintiffs, fact issues exist as to Plaintiffs’ claims for breach of the implied warranty of fitness for a particular purpose. DePuy’s motion on this claim is, therefore, **DENIED**.

Res Ipsa Loquitur

Plaintiffs do not concede that *res ipsa loquitur* is not a cause of action under Montana law. But, they do represent to this Court that they do not intend to seek separate relief or a separate jury question with respect to *res ipsa loquitur*. Instead, Plaintiffs intend to request an evidentiary instruction under the Montana Pattern Jury Instructions based on *res ipsa loquitur*. It is DePuy’s position that the proper procedure to have the doctrine of *res ipsa loquitur* applied to Plaintiffs’ case is to make the appropriate showing and seek a jury instruction as part of their negligence claim at trial. Accordingly, this Court need not address DePuy’s argument that *res ipsa loquitur* is not a cause of action under Montana law.

E. DePuy's Motion for Partial Summary Judgment on Plaintiffs' Design Defect Claims.

DePuy moves for partial summary judgment on Count II of the Lay Second Amended Complaint and Count I of the Paoli Second Amended Complaint, "Strict Product Liability (Design Defect)." DePuy contends that these state law claims are preempted by federal law under the Supreme Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580-81 (2011) due to an impossible conflict between state and federal law. Plaintiffs seek to recover from DePuy in strict liability under Montana law based on allegations that the metal-on-metal Pinnacle Device is unreasonably dangerous for its intended purpose and, therefore, defective. But DePuy contends it cannot redesign the Pinnacle Device; it must seek permission to change the design from the federal government, which is dependent on the exercise of judgment by a federal agency. DePuy alleges that the state and federal law applicable in this case conflict because it is impossible for it to independently comply with both state and federal requirements. DePuy, therefore, argues that the state law claims are preempted under *Mensing*.

DePuy's arguments must fail as a matter of law. *Mensing* involved the preemption of failure to warn claims for generic prescription drugs as opposed to medical devices. The FDA must pass on the safety of drugs and the accompanying warnings before a drug can be marketed. Liability must be predicated only on the manufacturer's ability to unilaterally make changes after government approval of the warning. *Id.* The state law claims in *Mensing* were, therefore, preempted. *Id.*

Because this case involves a medical device and not prescription drugs, DePuy's argument is foreclosed by the Supreme Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). That case involved a medical device (pacemaker). Under the Medical Device Act ("MDA"), medical devices may be cleared by the federal government for use in two different methods: (1) premarket approval whereby the manufacturer must provide the FDA with reasonable assurance that the device is safe and effective and (2) section 510(k) notification to the FDA that the device is substantially equivalent to a pre-existing device. *Id.* at 477-78. Under the second method, the device can be marketed without further regulatory analysis. *Id.* The *Lohr* Court held that state law design defect claims are not preempted by the MDA for devices cleared through section 510(k), the same process used to clear the Pinnacle Device, because the MDA imposes no design requirements on the manufacturer. *Id.* at 493-94.

Lohr is controlling in this case. The undisputed summary judgment evidence shows that like the device at issue in *Lohr*, the Pinnacle Device was cleared through the section 510(k) process rather than premarket approval. The FDA never passed on the original design of the device and imposed no requirements for safety or otherwise on it. The FDA merely determined whether the Pinnacle Device was substantially equivalent to a grandfathered device. DePuy, therefore, could not have been subject to conflicting state and federal design requirements. DePuy's motion for partial summary judgment on Plaintiffs' strict liability design defect claims is **DENIED**.

IV. CONCLUSION

DePuy has pointed out numerous issues with respect to Plaintiffs' claims in this case. This Court finds, however, that for purposes of summary judgment, the evidence when viewed in the light most favorable to Plaintiffs raises fact issues such that a reasonable jury could return a verdict for Plaintiffs. Defendants' motions to dismiss and for summary judgment are **DENIED**.

SO ORDERED.

Signed July 18, 2014.

A handwritten signature in cursive script, reading "Ed Kinkeade", written in dark ink.

ED KINKEADE
UNITED STATES DISTRICT JUDGE